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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/634,082	08/08/2000	Keith D. Beaty	47168-00068USCI	5448

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/634,082	BEATY, KEITH D.
	Examiner	Art Unit
	Julian W. Woo	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 June 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 90-142 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 134-136 is/are allowed.
- 6) Claim(s) 90-133 and 137-142 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2,5,7</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 96 and 101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claim 96, line 2, "said lower end" and "said upper end" lack antecedent bases. With respect to claim 101, line 2, "said electrical power" lacks antecedent basis.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 90-97 and 106-109 are rejected under 35 U.S.C. 102(e) as being anticipated by Garfinkel (5,577,911). Garfinkel discloses, in the figures and in col. 2, lines 47-63 and in col. 3, lines 19-36, a device for developing a bore in living bone,

where the device has an osteotome or compaction tool (14) with a central axis and a surface for compacting bone, a driving mechanism (20) with a piezoelectric transducer element and a cone-shaped mechanical coupling component (at interface of 22 and 16), a power source ("AC electrical outlet"), coupling means (16) with means for releasing and attaching the tool to the driving mechanism, vibrational motion is the direction of the central axis (see col. 2, lines 40 and 41), a drive rod (22) between the piezoelectric transducer and the coupling means, a tool segment with a constant cross-section (see fig. 4A or 4D), a tool cross-section that is tapered or increases from a lower end to an upper end (see fig. 4D), and a coupling means with a screw element (thread) extending into the tool. Note: The introductory statement of intended use("for developing a bore in living bone")has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over Garfinkel's device, which is capable of being used as claimed if one desires to do so.

4. Claims 98-100, 102, 103, 110, 111, 113, 131-133, and 137-142 are rejected under 35 U.S.C. 102(a) as being anticipated by Hahn (6,139,320). Hahn discloses in figures 1 and 13 and in col. 2, lines 21-26; col. 4, lines 12-19; and col. 16, lines 53-59; a compaction tool and a method as claimed for developing a bore in a living bone (150), where the method includes the application of an osteotome or compaction tool (154) or a tool, a driving mechanism (16) with a piezoelectric transducer element, and vibrational motion with an amplitude less than 1.0 mm (see col. 12, lines 43-45); and where the tool includes a central axis, a sequence of regions from the lower end to the upper end that

increases in cross-sectional area or is tapered (at the spherical portion), and regions of constant diameter (152).

5. Claims 116-126, and 128-130 are rejected under 35 U.S.C. 102(b) as being anticipated by Idemoto et al. (4,832,683). Idemoto et al. disclose, in the figures and in col. 3, lines 37-60, a device and a method for applying the device in developing a bore in a living bone (28), where the device includes a tool having a central axis, a generally circular cutting edge, a gradually expanding region behind the cutting edge, a region of constant diameter (at 30), a conduit (21), and a concave surface (22); a driving mechanism (4) with a piezoelectric (electrostriction) device, and electrical power at a selected frequency and amplitude (see col. 3, lines 37-42).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 101,104, and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Idemoto et al. Hahn discloses the invention substantially as claimed, but does not disclose a method where the piezoelectric transducer element oscillates when electrical oscillations of a selected frequency and amplitude are produced by electric power and where vibrational motion of the tool has a frequency of 500 Hz. Idemoto et al. teach, in col. 3, lines 37-60, transducer element oscillations from electrical oscillations produced by electric power and variable vibrational motion frequencies. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Idemoto et al., to control the transducer element oscillations via control of electrical power frequencies and choose a vibrational motion frequency of 500 Hz. Such control of transducer element oscillations and the choice of a vibrational motion frequency would be applied according to conditions of the operation to be performed, including for example, tissue hardness.

8. Claims 112, 114, and 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn. Hahn discloses the invention substantially as claimed, but does not disclose an osteotome tool engaging living bone substantially along an entire length of a bore in the bone, the tool incrementally compacting bone, and the step of developing a pilot hole before insertion of the tool in the hole. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to engage the tool along the length of the bore. Such a practice would be applied, if upon necessity, a bore is formed that is large enough to accommodate a substantial portion of the tool. Also, formation of the bore inherently causes some

compaction of bone material by the tool, so incremental formation of the bore would lead to incremental compaction of the living bone. It would also be obvious to develop a pilot hole before insertion of a tool. A pilot hole would allow positionally precise boring into bone through guidance of the tool along the axis of the hole.

9. Claim 127 is rejected under 35 U.S.C. 103(a) as being unpatentable over Idemoto et al. Idemoto et al. disclose the invention substantially as claimed, but do not disclose a method with a tool having a vibrational motion frequency of about 500 Hz. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to choose such a frequency. Such a choice would be dependent upon conditions of the operation to be performed, including for example, tissue hardness. A choice of 500 Hz would be useful for cutting soft tissue without undue damage to the tissue.

Allowable Subject Matter

10. Claims 134-136 are allowed.

11. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a method of installing a dental implant into a bore in living bone, where the method includes developing the bore with an osteome tool having piezoelectric transducer element as a driving mechanism and where a dental implant is screwed into the bore.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gayso (3,898,739) teach a vibrating, compacting tool. Young et al. (5,536,266) teach a cutting tool with a piezoelectric transducer. Vlacancich (5,529,494) teaches a method of installing a dental implant into bone.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)872-9302.



Julian W. Woo
Patent Examiner

March 18, 2003